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# A Retrospective Analysis of Tofacitinib Use in Patients with Spondyloarthritis

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**ABSTRACT**
Spondyloarthritis (SpA) is a chronic inflammatory rheumatic disorder associated with progressive disability, impaired mobility, and reduced quality of life. Tofacitinib, an oral Janus kinase inhibitor, has emerged as a potential therapeutic option; however, real-world outcome data remain limited. This retrospective, single-arm observational study evaluated the efficacy, safety, and tolerability of tofacitinib in 100 adult SpA patients attending a tertiary-care rheumatology centre. Demographic, laboratory, and treatment data were obtained from medical records. The majority of patients were male (76%), and 29% were HLA-B27 positive. Weight gain (76%), elevated ALT (54%), and increased serum creatinine (52%) were the most frequently observed adverse events, whereas herpes zoster occurred in only 2% of patients. Overall, tofacitinib demonstrated acceptable tolerability, with manageable safety signals under appropriate monitoring. The findings support the clinical utility of tofacitinib in the management of spondyloarthritis while underscoring the need for prospective, controlled studies to confirm long-term safety and comparative efficacy.
**Keywords:** Spondyloarthritis (SpA), Tofacitinib, serum creatinine, Demographic, laboratory, spondyloarthritis

## INTRODUCTION

Spondyloarthritis (SpA) is a chronic inflammatory rheumatic disease associated with progressive disability, impaired mobility, and reduced quality of life. Although biologic therapies have significantly improved clinical outcomes, a proportion of patients either fail to respond or remain inadequately controlled. Tofacitinib, an orally administered Janus kinase inhibitor, has emerged as a promising therapeutic option. The present retrospective observational study was undertaken to evaluate the efficacy, safety, and tolerability of tofacitinib among patients diagnosed with spondyloarthritis in a real-world clinical setting at a tertiary care hospital.

A total of 100 adult patients were included in the study. The majority were male (76%), consistent with known epidemiological trends. HLA-B27 positivity was observed in 29% of participants, reflecting the variable serological profile of SpA in clinical practice. Prior treatment exposure revealed that 27% of patients had previously received conventional synthetic DMARDs, whereas 10% had been treated with biologic therapy. Notably, 71% of patients were receiving tofacitinib as their principal ongoing therapy. The analysis of adverse events demonstrated that the most commonly reported effect was weight gain (76%), followed by elevated ALT (54%) and increased serum creatinine (52%). Reductions in hemoglobin were documented in 14% of patients. Infectious complications were relatively infrequent, with upper respiratory tract infections reported in 10% and herpes zoster in only 2% of patients. Statistical comparison indicated significant variations among adverse event frequencies, highlighting the need for clinical vigilance and periodic laboratory monitoring.

Overall, the findings indicate that tofacitinib is being utilized successfully in routine clinical practice for the management of spondyloarthritis, particularly in patients where alternative therapies may be unsuitable or insufficient. The observed safety profile was generally acceptable and comparable with existing literature, with serious adverse effects being uncommon.

## METHODOLOGY

### Materials and Methods

This study will utilize data obtained from patient medical records, laboratory reports, prescription records, and direct communication with treating healthcare professionals. All relevant clinical and demographic information pertaining to eligible patients diagnosed with spondyloarthritis and initiated on tofacitinib therapy will be systematically extracted and documented using a structured data collection format.

### Study Setting

The study will be conducted in the Out-Patient Department of Clinical Immunology and Rheumatology, Krishna Institute of Medical Sciences (KIMS) Hospital, Secunderabad, Telangana, India. This tertiary care referral centre receives a wide spectrum of autoimmune and rheumatological cases, providing an appropriate patient base for retrospective data analysis.

**Study Design:** This study is designed as a retrospective, single-arm, observational study. Patient records will be reviewed to evaluate the clinical response, safety outcomes, and tolerability of tofacitinib in individuals diagnosed with spondyloarthritis during the specified study period. No interventional procedures /randomization will be undertaken.

### Ethical Considerations

Prior to initiation, approval will be obtained from the Institutional Ethics Committee (IEC) of Krishna Institute of Medical Sciences. Permission will also be sought from the Head of the Department of Clinical Immunology and Rheumatology. The study will strictly adhere to the principles of the Declaration of Helsinki, institutional research policies, and applicable national ethical guidelines. Confidentiality of patient identity and medical information will be maintained at all times. Data will be anonymized, coded, and used exclusively for academic and research purposes. No direct patient contact or alteration of therapy will occur as part of this study.

**Study Period**

The retrospective study will cover a six-month duration, during which eligible patient data will be retrieved, compiled, and analyzed.

**Study Population and Sample Size**

A minimum sample size of 100 adult patients diagnosed with spondyloarthritis and treated with tofacitinib will be included. Records of all eligible patients meeting inclusion criteria during the defined period will be reviewed until the required sample size is reached. This sample size is considered adequate to enable meaningful descriptive and comparative analysis of safety and efficacy outcomes in a real-world clinical setting.

**Data Source and Collection Procedure**

**Data will be collected from:**

- Outpatient consultation records
- Laboratory investigation reports
- Prescription and medication charts
- Radiological reports (where available)
- Clinical documentation by treating rheumatologists
- Follow-up visit notes

Information will be documented in a pre-designed data collection form. Clarification, when required, will be obtained through consultation with treating healthcare professionals.

**Inclusion Criteria**

- Adult patients (≥18 years of age)
- Diagnosed with spondyloarthritis as per established clinical criteria
- Receiving tofacitinib therapy during the study period
- Complete medical records available for review

**Exclusion Criteria**

- Patients with incomplete or missing medical records
- Patients receiving investigational or combination biologic therapy
- Individuals with alternative rheumatologic diagnoses
- Pregnant or lactating women

**Study Variables**

Data collected will include:

- Demographic details (age, sex, occupation)
- Disease characteristics (duration, subtype, comorbidities)
- Medication details (dose, duration of tofacitinib therapy)
- Laboratory parameters (ESR, CRP, hematology, liver/renal function)
- Clinical disease activity scores (where available)
- Adverse drug reactions
- Treatment discontinuation or modification
- Quality-of-life assessments (if recorded)

**Outcome Measures**

Primary and secondary endpoints will be evaluated as per study objectives and include clinical response, tolerability, quality-of-life impact, and adverse events.

**Data Handling and Confidentiality**

All data will be securely stored and accessible only to authorized research personnel. Patient identifiers will be omitted during analysis, and results will be presented in aggregated form to ensure privacy protection.

**Statistical Analysis**

Data will be entered into an appropriate statistical software program. Descriptive statistics will be used to summarize patient demographics, baseline characteristics, and treatment outcomes. Continuous variables will be expressed as mean ± standard deviation or median values, while categorical variables will be represented as frequencies and percentages. Comparative analyses may be conducted where applicable to assess treatment response and safety outcomes.

**Summary**

This retrospective observational design enables evaluation of real-world therapeutic outcomes of tofacitinib in spondyloarthritis without influencing clinical practice patterns. The methodology ensures ethical integrity, confidentiality, and systematic data analysis to provide meaningful clinical evidence.

## RESULTS AND DISCUSSION

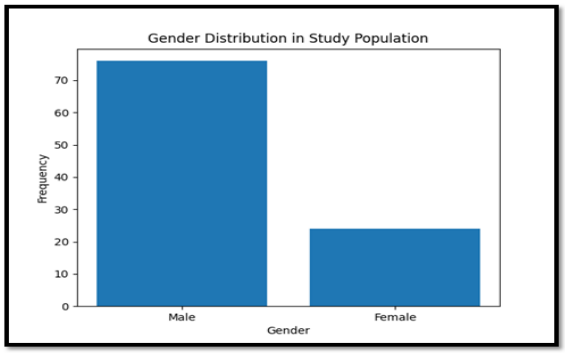


**Fig.1:** Gender Distribution

**Table 1:** Gender Distribution

| Gender | Frequency | Percentage |
|---|---|---|
| Male | 76 | 76% |
| Female | 24 | 24% |

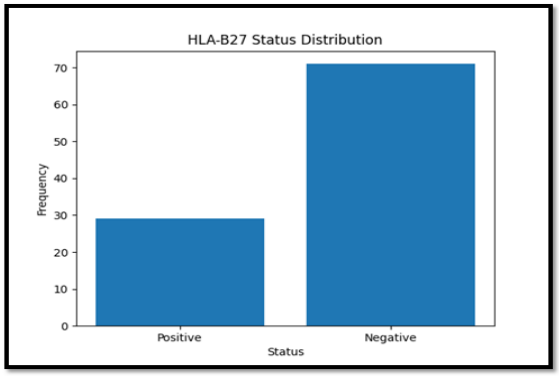


**Fig.2:** HLA-B27 Status

**Table 2:** HLA-B27 Status

| HLA Status | Frequency | Percentage |
|---|---|---|
| Positive | 29 | 29% |
| Negative | 71 | 71% |

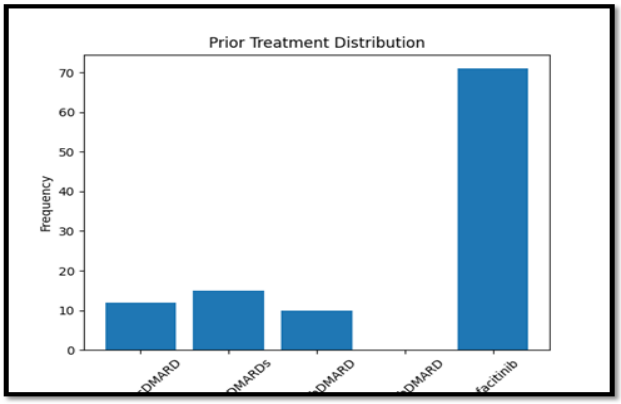


**Fig.3:** Prior Treatment Exposure

**Table 3:** Prior Treatment Exposure

| Treatment Type | Frequency | Percentage |
|---|---|---|
| Prior 1 csDMARD | 12 | 12% |
| Prior 2 csDMARDs | 15 | 15% |
| Prior 1 bDMARD | 10 | 10% |
| Prior 2 bDMARD | 0 | 0% |
| Tofacitinib Monotherapy | 71 | 71% |

$p < 0.001$ indicates that the majority of patients were directly initiated or stabilized on Tofacitinib therapy

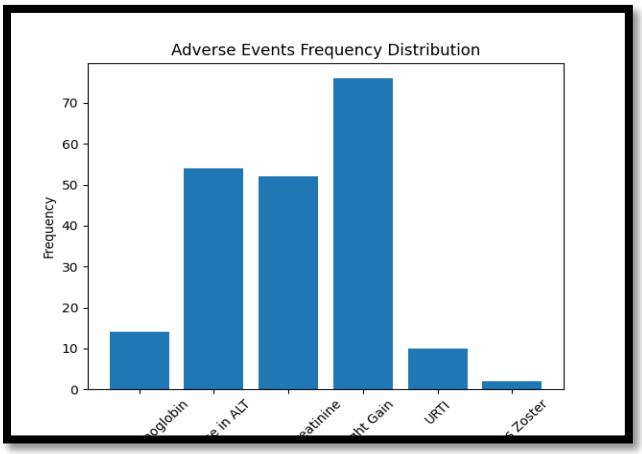


**Fig.4:** Adverse Events

**Table 4: Adverse Events**

| Adverse Event | Frequency | Percentage |
|---|---|---|
| Drop in Hemoglobin | 14 | 14% |
| Increase in ALT | 54 | 54% |
| Increase in Creatinine | 52 | 52% |
| Weight Gain | 76 | 76% |
| URTI | 10 | 10% |
| Herpes Zoster | 2 | 2% |

Weight gain was significantly more frequent compared to other adverse events ($p < 0.001$).

## Discussion

The present retrospective observational study evaluated the safety and clinical outcomes of tofacitinib therapy in patients with spondyloarthritis managed in a real-world setting. A male predominance was noted (76%), consistent with established literature indicating higher reported prevalence of axial spondyloarthritis among males. However, increasing awareness has improved diagnosis among female patients in recent years. The mean distribution suggests that disease recognition remains high among working-age adults, reflecting the chronic and function-limiting nature of the disorder. HLA-B27 positivity was identified in only 29% of patients. Although HLA-B27 remains a major genetic marker, its prevalence varies geographically and is lower in some Asian populations. Furthermore, HLA-B27 negative disease is increasingly recognized, especially in patients with non-radiographic or late-onset disease. Prior treatment data indicate that a significant proportion of patients (27%) had previously been exposed to csDMARDs and 10% to biologic therapy. This suggests that tofacitinib is being utilized both as a primary advanced therapy and as an alternative in treatment-refractory cases. The preference for oral therapy may also influence clinician prescribing trends and patient adherence.

Adverse event analysis showed that metabolic and biochemical changes were more commonly observed compared with infectious complications. Weight gain was the most frequent adverse outcome, followed by laboratory abnormalities including elevated ALT and creatinine. These findings emphasize the need for periodic laboratory monitoring and counselling on lifestyle modification during therapy. Importantly, clinically significant infections were relatively uncommon, with herpes zoster occurring in only 2% of patients. These findings reinforce emerging evidence supporting the safety and tolerability of tofacitinib in spondyloarthritis. Real-world datasets such as this are particularly valuable because they include heterogeneous patient groups often excluded from randomized clinical trials. The study highlights the importance of ongoing pharmacovigilance, structured monitoring, and individualized patient assessment when prescribing JAK inhibitors.

## CONCLUSION

The present study provides supportive real-world evidence that tofacitinib is an effective and generally well-tolerated therapeutic option for the management of spondyloarthritis. The drug demonstrated widespread clinical use within the study population, including in patients with prior exposure to csDMARDs and biologic agents. Although adverse events were observed, the majority were manageable with appropriate monitoring and did not limit overall treatment continuation in most patients. Male predominance and variable HLA-B27 expression patterns were consistent with known epidemiological trends. Importantly, the study highlights the increasing role of targeted synthetic DMARDs such as tofacitinib in modern SpA treatment algorithms, especially due to the advantages of oral administration and broader cytokine pathway modulation. However, as a retrospective single-arm study, the findings should be interpreted with caution. The lack of a comparator group and reliance on medical records represent inherent methodological limitations. Larger prospective controlled studies are recommended to further validate the long-term safety and efficacy of tofacitinib, particularly regarding metabolic and biochemical adverse effects. Despite these limitations, the study contributes valuable real-world evidence that supports

the clinical utility of tofacitinib in appropriately selected patients with spondyloarthritis. Continued pharmacovigilance, patient education, and individualized therapy selection remain essential to optimizing treatment outcomes.

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## CONFLICT OF INTERESTS
The authors declare no conflict of interest

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## AI TOOL DECLARATION
The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

## DATA AVAILABILITY
Data will be available on request

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